TIME SENSITIVE PATENT INFORMATION PURSUANT TO 21 C.F.R. 314.53 (c) FOR NDA # 20-553

The following is provided in accordance with the Drug Price Competition and Patent Term Restoration Act of 1984:

Trade Name:

Approval Date:

OxyContin®

Active Ingredient(s):

Oxycodone Hydrochloride 10, 20, 40, 80 and 160 mg

Strength(s):
Dosage Form:

Extended-Release Tablets

10 mg. - December 12, 1995 20 mg. - December 12, 1995 40 mg. - December 12, 1995 80 mg. - January 6, 1997 160 mg. - March 15, 2000

Applicant:

Purdue Pharma L.P.

One Stamford Forum Stamford, CT 06901-3431

Listed Drug:

OxyContin® (Oxycodone Hydrocloride) Controlled-Release Tablets

Indication(s):

OxyContin® (Oxycodone Hydrocloride) Controlled-Release Tablets are indicated for the management of moderate to severe pain when a continuous,

around-the-clock analgesic is needed for an extended period of time.

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Trial Exhibit

Purdue et al. v. Endo et al.

Nos. 00 Civ. 8029 (SHS);

01 Civ. 2109 (SHS); 01 Civ. 8177 (SHS)

DX 4110

1.

United	States Patent No. 4,861,598		
A	This information should be provided for each individual patent submitted:		
	U.S. Patent Number:	4,861,598	
	Expiration Date:	August 29, 2006	
	Type of Patent (indicate all that apply):		
	Drug Substance (Active Ingredient) Drug Product (Composition/Formulation) Method of Use Y X N Y N N		
	a. If patent claims me method(s) of use for N/A	thod(s) of use, please specify approved method(s) of use or which approval is being sought that are covered by patent:	
Name of Patent Owner: Euro-Celtique S.A.			
U.S. A	gent (if patent owner or appli C. Strassburger, Purdue Phan	icant does not reside or have place of business in the U.S.): na L.P., 1 Stamford Forum, Stamford, CT 06901-3431	
В.	The following declaration statement is required by 21 C.F.R. 314.53. If any of the submitted patents have Composition/Formulation or Method of Use claims, it should be submitted for each patent that contains composition/formulation or method of use claims.		
	The undersigned declares that the above stated United States Number 4,861,598 covers the composition, formulation and/or method of use of all strengths of OxyContin® Controlled-Release Tablets. This product is:		
	x currently approved under section 505 of the Federal Food, Drug and Cosmetic Act.		
	OR		
	the subject of this appli	cation for which approval is being sought.	

Confidential Information
Purdue v. Endo

2.

United	States Patent No. 4,970,075	5
A.	This information should be	provided for each individual patent submitted:
	U.S. Patent Number:	4,970,075
	Expiration Date:	August 29, 2006
	Type of Patent (indicate all	that apply):
	Drug Substance (Active Ing Drug Product (Composition Method of Use	redient) Y X Y N Y N Y N Y N Y N Y N Y N Y N Y N
	a. If patent claims method(s) of use for N/A.	ethod(s) of use, please specify approved method(s) of use or or which approval is being sought that are covered by patent:
Name	of Patent Owner:	Euro-Celtique S.A.
U.S. A	Agent (if patent owner or appl C Strassburger, Purdue Phar	licant does not reside or have place of business in the U.S.): ma L.P., 1 Stamford Forum, Stamford, CT 06901-3431
В.	The following declaration	statement is required by 21 C.F.R. 314.53. If any of the imposition/Formulation or Method of Use claims, it should be not contains composition/formulation or method of use claims.
	The undersigned declares the composition, formulat Controlled-Release Tablets	that the above stated United States Number 4,970,075 cover ion and/or method of use of all strengths of OxyConting. This product is:
	x currently approved un	der section 505 of the Federal Food, Drug and Cosmetic Act.
	OR	
	the subject of this appl	ication for which approval is being sought.

Confidential Information <u>Purdue v. Endo</u> 3.

United	States	Patent No. 5,266,33	11
A.	This information should be provided for each individual patent submitted:		
	U.S. P	atent Number:	<u>5,266,331</u>
	Ехріга	tion Date:	October 26, 2007
	Type of Patent (indicate all that		l that apply):
	Drug Substance (Active Ingredient) Drug Product (Composition/Formulation) Method of Use Y X N Y N Y N		
	a .	If patent claims method(s) of use for N/A	nethod(s) of use, please specify approved method(s) of use or or which approval is being sought that are covered by patent:
Name of Patent Owner: Purdue Pharma L.P. The Purdue Frederick Company The P.F. Laboratories, Inc. The Purdue Pharma Company			
U.S. A	gent (if) C. Strasi	patent owner or app sburger, Purdue Pha	olicant does not reside or have place of business in the U.S.): 1772 Trans L.P., 1 Stamford Forum, Stamford, CI 06901-3431
В	The following declaration statement is required by 21 C.F.R. 314.53. If any of the submitted patents have Composition/Formulation or Method of Use claims, it should be submitted for each patent that contains composition/formulation or method of use claims.		
	The undersigned declares that the above stated United States Number 5,266,331 covers the composition, formulation and/or method of use of all strengths of OxyContin® Controlled-Release Tablets. This product is:		
	X CI	urently approved u	nder section 505 of the Federal Food, Drug and Cosmetic Act.
	OR		
the subject of this application for which approval is being sought.			

Confidential Information
<u>Purdue v. Endo</u>

Inited	States	Patent No. 5,508,0	42		
٩.	This in	formation should b	e provided for each in	ndividual patent submitted:	
	U.S. P	atent Number:	<u>5.508.042</u>		
	Expira	tion Date:	April 16, 2013		
	Type	of Patent (indicate o	ill that apply):		
	Drug I	Substance (Active In Product (Composition of Use	ngredient) on/Formulation)	YN YN	
	a.	method(s) of use Management of	for which approval is	ease specify approved method(s) of use of being sought that are covered by patent pain when a continuous, around-the-clock riod of time.	
Name	of Paten	at Owner:	The P.F. Labo	rederick Company	
U.S. A Philip	gent (if C. Stras	patent owner or ap sburger, Purdue Ph	plicant does not resid	de or have place of business in the U.S.): d Forum, Stamford, CT 06901-3431	
В.	The fo	ollowing declaration	on statement is requi	ired by 21 C.F.R. 314.53. If any of the tion or Method of Use claims, it should be sition/formulation or method of use claims	Œ
	the co	imposition, formul	s that the above state ation and/or method ats. This product is:	ed United States Number 5,508,042 cover d of use of all strengths of OxyContine	8
	X c	urrently approved t	ınder section 505 of t	the Federal Food, Drug and Cosmetic Act.	
	OR				
	th	c subject of this ap	plication for which ap	pproval is being sought.	

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Purdue v. Endo

_	TI_:4-	ed States Patent No. 5,549,91	12		
5.			•		
	A.	This information should be	This information should be provided for each individual patent submitted:		
		U.S. Patent Number:	<u>5,549.912</u>		
		Expiration Date:	October 26, 2007		
	Type of Patent (indicate all that apply):		ll that apply):		
		Drug Substance (Active In Drug Product (Composition Method of Use	ngredient)Yx _N on/Formulation)YX _NYN		
		a. If patent claims r method(s) of use t N/A.	nethod(s) of use, please specify approved method(s) of use or which approval is being sought that are covered by patent:		
	Marn	e of Patent Owner:	Purdue Pharma L.P.		
	LASUI	e of I atom owner.	The Purdue Frederick Company		
			The P.F. Laboratories, Inc.		
			The Purdue Pharma Company		
	U.S.	Agent (if patent owner or app	olicant does not reside or have place of husiness in the U.S.): arma L.P., 1 Stamford Forum, Stamford, CT 06901-3431		
	В.	mi . Callamina declaratio	n statement is required by 21 C.F.R. 314.53. If any of the		
	submitted patents have Composition/Formulation or Method of Use cla submitted for each patent that contains composition/formulation or meth		composition/Formulation of Method of Use clams, it should be		
		The undersigned declares the composition, formula Controlled-Release Table	s that the above stated United States Number 5,549,912 cover ation and/or method of use of all strengths of OxyContine is. This product is:		
		x currently approved u	inder section 505 of the Federal Food, Drug and Cosmetic Act.		

the subject of this application for which approval is being sought.

OR

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6.	United	States Patent No. 5,656,295
	A.	This information should be p

This information should be provided for each individual patent submitted:

U.S. Patent Number:

<u>5,656,295</u>

Expiration Date:

October 26, 2007

Type of Patent (indicate all that apply):

Drug Substance (Active Ingredient)
Drug Product (Composition/Formulation)
Method of Use

Y X N X Y N

a. If patent claims method(s) of use, please specify approved method(s) of use or method(s) of use for which approval is being sought that are covered by patent:

Management of moderate to severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time.

Name of Patent Owner:

Purduc Pharma L.P.

The Purdue Frederick Company
The P.F. Laboratories, Inc.
The Purdue Pharma Company

U.S. Agent (if patent owner or applicant does not reside or have place of business in the U.S.): Philip C. Strassburger. Purdue Pharma L.P., 1 Stamford Forum, Stamford, CT 06901-3431

B. The following declaration statement is required by 21 C.F.R. 314.53. If any of the submitted patents have Composition/Formulation or Method of Use claims, it should be submitted for each patent that contains composition/formulation or method of use claims.

The undersigned declares that the above stated United States Number 5,656,295 covers the composition, formulation and/or method of use of all strengths of OxyContin® Controlled-Release Tablets. This product is:

x currently approved under section 505 of the Federal Food, Drug and Cosmetic Act.

OR

the subject of this application for which approval is being sought.

Signed:

Philip C. Strassburger

U.S. Patent and Trademark Office Registration No. 34,258

Date: March 28, 2002

Title: Vice President, Intellectual Property Counsel

Purdue Pharma L.P.

Telephone Number:

(203) 588-7639

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